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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,631	02/10/2004	Kevin S. Currie	09580.0008-00000	1748

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EXAMINER	
TUCKER, ZACHARY C	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,631	CURRIE ET AL.	
	Examiner	Art Unit	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-60 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10May,5Nov04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-35 and 60, drawn to chemical compounds having the imidazo[1,2-a]pyrazine core, classified in class/subclass 544/350

II. Claims 44-56, drawn to methods of modulating the binding of ATP to Hsp90 complex, and also treatment of various diseases or disorders, classified in class/subclass 514/249.

III. Claims 57-59, drawn to a method for detecting the presence or absence of Hsp90 *in vitro*, classified in class/subclass 435/4+.

IV. Claims 36-42, drawn to a pharmaceutical composition, classified in class/subclass 514/249 and to a packaged pharmaceutical composition classified in class/subclass 206/828.

V. Claim 43, drawn to a method of reducing medication error and enhancing therapeutic compliance, classified in class 705.

The inventions are distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, binding of ATP with Hsp90 complex may be modulated with compounds other than Group I compounds. Geldanamycin is an example of such a materially different compound. Diseases and

conditions which are (allegedly) treatable with Group I compounds are treatable with materially different chemical compounds. To wit, cancers (as specified in the method of instant claim 54) are treatable with surgery and cytotoxic agents.

Inventions I and III are also related as product and process of use. Methods according to Group III are not commensurate in scope with Group II methods, however, because of the additional step of detection in those methods. Hsp90 complex is detectable by methodologies different than those according to instant claims 57-59, such as by Western blot.

Inventions I and IV are related as product and sub-product. They are patentably distinct because Group I compounds are not limited in their utility only to active ingredients in pharmaceutical compositions. The compounds according to the invention are useful for *in vitro* assay of Hsp90 as well.

Inventions IV and V are related as product and process of using. The two inventions are patentably distinct because packaged pharmaceutical compositions according to Group IV are not limited in their utility only to reduction of medication errors and enhancing therapeutic compliance. Packaged pharmaceutical compositions according to Group IV are (allegedly) useful also for treatment of diseases.

This Requirement is subject to the following conditions:

The examiner has required restriction between compounds, pharmaceutical compositions, and method of use claims. Where applicant elects claims directed to compounds, and a compound claim is subsequently found allowable, withdrawn pharmaceutical composition claims and method of use claims that depend from or otherwise include all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Pharmaceutical composition claims and method of use claims that depend from or otherwise include all the limitations of the patentable compound** will be entered as a matter of right if the

amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the compound claims and the rejoined pharmaceutical composition claims and method of use claims will be withdrawn, and the rejoined pharmaceutical composition and method of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected compound claim is found allowable, an otherwise proper restriction requirement between compound claims, pharmaceutical composition claims and method of use claims may be maintained. Withdrawn pharmaceutical composition claims and method of use claims that are not commensurate in scope with an allowed compound claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the pharmaceutical composition claims and method of use claims should be amended during prosecution either to maintain dependency on the compound claims or to otherwise include the limitations of the compound claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

For the purposes of rejoinder, Groups II and V, should Group I be elected and subsequently found allowable, will be eligible for rejoinder. The remaining Groups are not seen as commensurate in scope.

Specification

The title of the invention is objected to under 37 C.F.R. 1.72, as it is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Much more than only 8-heteroary-6-phenyl-imidazo[1,2-a]pyrazine compounds are disclosed and claimed. Claim 1, for example, does not require the imidazo[1,2-a]pyrazine core to be phenyl-substituted at the 6-position and heteroaryl-substituted at the 8-position. If applicants wish to limit the claims to only the compounds described in the title, they are entitled to do so.

At pages 5 of the specification, the examiner notes a discussion of the variable "Z_1." The compounds as claimed include no such variable. Applicants should review the claims and the specification to determine whether something was omitted from the claims or included in the specification which is not germane to the claims.

Information Disclosure Statement

The Information Disclosure Statements filed on May 10 and 5 November 2004 have been considered, and signed and initialed forms PTO-1449 to that effect are enclosed herewith.

The last two cited items on the PTO-1449 form accompanying the IDS of 5 November 2004, and also the last cited item on page 2 of the PTO-1449 form accompanying the IDS filed 10 May 2004 have been read and understood the by the examiner, but are lined through, because the manner in which they are cited is not compliant with 37 C.F.R. 1.98, as no publication date is provided. Indeed, there is no publication date for any document, because none of the three is a publication.

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Tuesday-Thursday from 8:00am to 4:30pm or Monday from 6:00am to 1:30pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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